

D

1. An assay kit for use in analyzing a sample from an individual having, or suspected of having, a disease condition selected from the group consisting of multiple sclerosis ("MS"), a pro-MS immune response, and a combination thereof; the assay kit comprising a combination of two or more affinity ligands, wherein the affinity ligands are selected from the group consisting of an anti-human antibody, an affinity ligand having binding specificity for a member of the sialoadhesin family, and an affinity ligand having binding specificity for an epitope comprising a terminal alpha 2,6-linked sialic acid.

*unfilled
used
in
fluorophores
cyclic
immobilized
solid*

2. The assay kit according to claim 1, wherein at least one of the affinity ligands comprises a detection reagent.

3. The assay kit according to claim 2, wherein at least one of the affinity ligands comprising the detection reagent further comprises a detectable moiety.

4. The assay kit according to claim 1, wherein at least one of the affinity ligands comprises an affinity ligand immobilized to a solid phase.

5. The assay kit according to claim 1, wherein the anti-human antibody is selected from the group consisting of an anti-human IgG monoclonal antibody ("mAb"), an anti-human IgM mAb, and a combination thereof.

6. The assay kit according to claim 1, wherein the affinity ligand having binding specificity for an epitope comprising

a terminal alpha 2,6-linked sialic acid comprises an anti-sTn mAb.

7. The assay kit according to claim 1, wherein the affinity ligand having binding specificity for a member of the sialoadhesin family comprises an affinity ligand selected from the group consisting of an anti-human myelin-associated glycoprotein ("MAG") mAb, an anti-CD22 mAb, and a combination thereof.

8. The assay kit according to claim 1, wherein the combination of two or more affinity ligands is a combination selected from the group consisting of an antibody which specifically binds an epitope comprising a terminal alpha 2,6-linked sialic acid ("anti- α (2,6)NeuAc Ab") and an anti-human IgG mAb, anti-sTn mAb and anti-human IgG mAb, anti-human MAG mAb and anti-human IgM mAb, anti-human MAG mAb and anti-human IgG mAb, anti-human MAG mAb and anti- α (2,6)NeuAc Ab, anti-human MAG mAb and anti-sTn mAb, anti-human MAG mAb and anti-human CD22 mAb, anti-human CD22 mAb and anti-human IgM mAb, anti-human CD22 mAb and anti- α (2,6) NeuAc Ab, anti-human CD22 mAb and anti-sTn mAb, and a combination thereof.

Open
select
combine

9. The assay kit according to claim 1, further comprising a reference standard comprising a known amount of sialocomplexes which are detectable by the combination of two or more affinity ligands.

~~H~~ 10. A method for assaying a sample of an individual for an indicator of a disease condition selected from the group consisting of MS, a pro-MS immune response, and a combination thereof, the method comprising:

- (a) admixing an aliquot of sample under biological assay conditions with a combination of two or more affinity ligands, wherein the two or more affinity ligands are selected from the group consisting of an anti-human antibody, an affinity ligand having binding specificity for a sialoadhesin family member, and an affinity ligand having binding specificity for an epitope comprising a terminal alpha 2,6-linked sialic acid, and wherein at least one of the affinity ligands comprises a detection reagent;
- (b) measuring an amount of the detection reagent, if present, which is bound to the sample in determining a value of a marker in the sample;
- (c) comparing the value of the marker determined to a comparative reference value;
wherein a difference in the value of the marker determined in the sample, when compared to the reference value, comprises an indicator of the presence of the disease condition.

11. The method according to claim 10, wherein the sample is selected from the group consisting of plasma, and serum.

12. The method according to claim 10, wherein at least one of the affinity ligands comprising the detection reagent further comprises a detectable moiety.

13. The method according to claim 10, wherein at least one of the affinity ligands comprises an affinity ligand immobilized to a solid phase.
14. The method according to claim 10, wherein the anti-human antibody is selected from the group consisting of an anti-human IgG mAb, an anti-human IgM mAb, and a combination thereof.
15. The method according to claim 10, wherein the affinity ligand having binding specificity for an epitope comprising a terminal alpha 2,6-linked sialic acid comprises an anti-sTn mAb.
16. The method according to claim 10, wherein the affinity ligand having binding specificity for a member of the sialoadhesin family comprises an affinity ligand selected from the group consisting of an anti-human MAG mAb, an anti-CD22 mAb, and a combination thereof.
17. The method according to claim 10, wherein the combination of two or more affinity ligands is a combination selected from the group consisting of anti- $\alpha(2,6)$ NeuAc Ab and an anti-human IgG mAb, anti-sTn mAb and anti-human IgG mAb, anti-human MAG mAb and anti-human IgM mAb, anti-human MAG mAb and anti-human IgG mAb, anti-human MAG mAb and anti- $\alpha(2,6)$ NeuAc Ab, anti-human MAG mAb and anti-sTn mAb, anti-human MAG mAb and anti-human CD22 mAb, anti-human CD22 mAb and anti-human IgM mAb, anti-human CD22 mAb and anti-human IgG mAb, anti-human CD22 mAb and anti- $\alpha(2,6)$ NeuAc Ab,

anti-human CD22 mAb and anti-sTn mAb, and a combination thereof.

18. An indicator generated from the method according to claim 10.

19. A panel of indicators generated from the method according to claim 17.

20. A method for assaying a sample of an individual for monitoring the course of a disease condition selected from the group consisting of MS, a pro-MS immune response, and a combination thereof, the method comprising:

(a) admixing an aliquot of sample under biological assay conditions with a combination of two or more affinity ligands, wherein the two or more affinity ligands are selected from the group consisting of an anti-human antibody, an affinity ligand having binding specificity for a sialoadhesin family member, and an affinity ligand having binding specificity for an epitope comprising a terminal alpha 2,6-linked sialic acid, and wherein at least one of the affinity ligands comprises a detection reagent;

(b) measuring an amount of the detection reagent, if present, which is bound to the sample, in determining a value of a marker in the sample;

(c) comparing the value of the marker determined to a comparative value selected from the group consisting of a reference value, a baseline value, and a combination thereof;

wherein a difference in the value of the marker determined in the sample, when compared to the comparative value, comprises an indicator of a change in course of the disease condition.

21. The method according to claim 20, wherein an indicator generated from the method may be used in a process selected from the group consisting of prognostically, for monitoring any effect of treatment on the course of the disease condition, and or for predicting a response of the disease condition to a therapeutic agent.

22. The method according to claim 20, wherein the sample is selected from the group consisting of plasma, and serum.

23. The method according to claim 20, wherein at least one of the affinity ligands comprising the detection reagent further comprises a detectable moiety.

24. The method according to claim 20, wherein at least one of the affinity ligands comprises an affinity ligand immobilized to a solid phase.

25. The method according to claim 20, wherein the anti-human antibody is selected from the group consisting of an anti-human IgG mAb, an anti-human IgM mAb, and a combination thereof.

26. The method according to claim 20, wherein the affinity ligand having binding specificity for an epitope comprising

a terminal alpha 2,6-linked sialic acid comprises an anti-sTn mAb.

27. The method according to claim 20, wherein the affinity ligand having binding specificity for a member of the sialoadhesin family comprises an affinity ligand selected from the group consisting of an anti-human MAG mAb, an anti-CD22 mAb, and a combination thereof.

28. The method according to claim 20, wherein the combination of two or more affinity ligands is a combination selected from the group consisting of anti- α (2,6)NeuAc Ab and an anti-human IgG mAb, anti-sTn mAb and anti-human IgG mAb, anti-human MAG mAb and anti-human IgM mAb, anti-human MAG mAb and anti-human IgG mAb, anti-human MAG mAb and anti- α (2,6)NeuAc Ab, anti-human MAG mAb and anti-sTn mAb, anti-human MAG mAb and anti-human CD22 mAb, anti-human CD22 mAb and anti-human IgM mAb, anti-human CD22 mAb and anti-human IgG mAb, anti-human CD22 mAb and anti- α (2,6) NeuAc Ab, anti-human CD22 mAb and anti-sTn mAb, and a combination thereof.

*Select
Combination*

29. An indicator generated from the method according to claim 20.

30. A panel of indicators generated from the method according to claim 28.

31. A method for assaying a sample of body fluid from an individual for sialocomplexes, the method comprising:

(a) admixing an aliquot of the sample under biological assay conditions with a combination of two or more affinity ligands, wherein the two or more affinity ligands are selected from the group consisting of an anti-human antibody, an affinity ligand having binding specificity for a sialoadhesin family member, and an affinity ligand having binding specificity for an epitope comprising a terminal alpha 2,6-linked sialic acid, and wherein at least one of the affinity ligands comprises a detection reagent; and
(b) and measuring an amount of the detection reagent which is bound to sialocomplexes, if present, in determining an amount of the sialocomplexes.

32. The method according to claim 31, further comprising comparing the amount of sialocomplexes determined in the sample to a comparative value for the sialocomplexes, wherein the comparative value is selected from the group consisting of a reference value, a baseline value, and a combination thereof; wherein a difference in the amount of the sialocomplexes determined in the sample, when compared to the comparative value, comprises an indicator of a disease condition selected from the group consisting of MS, a pro-MS immune response, and a combination thereof.

33. The method according to claim 32, wherein an indicator generated from the method may be used in a process selected from the group consisting of prognostically, for monitoring any effect of treatment on the course of the disease condition, and or for predicting a response of the disease condition to a therapeutic agent.

34. The method according to claim 31, wherein the sample is selected from the group consisting of plasma, and serum.
35. The method according to claim 31, wherein at least one of the affinity ligands comprising the detection reagent further comprises a detectable moiety.
36. The method according to claim 31, wherein at least one of the affinity ligands comprises an affinity ligand immobilized to a solid phase.
37. The method according to claim 31, wherein the anti-human antibody is selected from the group consisting of an anti-human IgG mAb, an anti-human IgM mAb, and a combination thereof.
38. The method according to claim 31, wherein the affinity ligand having binding specificity for an epitope comprising a terminal alpha 2,6-linked sialic acid comprises an anti-sTn mAb.
39. The method according to claim 31, wherein the affinity ligand having binding specificity for a member of the sialoadhesin family comprises an affinity ligand selected from the group consisting of an anti-human MAG mAb, an anti-CD22 mAb, and a combination thereof.
40. The method according to claim 32, wherein the combination of two or more affinity ligands is a combination selected from the group consisting of anti- α (2,6)NeuAc Ab

and an anti-human IgG mAb, anti-sTn mAb and anti-human IgG mAb, anti-human MAG mAb and anti-human IgM mAb, anti-human MAG mAb and anti-human IgG mAb, anti-human MAG mAb and anti- α (2,6)NeuAc Ab, anti-human MAG mAb and anti-sTn mAb, anti-human MAG mAb and anti-human CD22 mAb, anti-human CD22 mAb and anti-human IgM mAb, anti-human CD22 mAb and anti-human IgG mAb, anti-human CD22 mAb and anti- α (2,6) NeuAc Ab, anti-human CD22 mAb and anti-sTn mAb, and a combination thereof.

~~41. An indicator generated from the method according to claim 32.~~

~~42. A panel of indicators generated from the method according to claim 40.~~

~~43. A method of removing sialocomplexes from the blood of an individual, the method comprising:~~

~~(a) collecting peripheral blood from the individual;~~
~~(b) separating plasma from the peripheral blood;~~
~~(c) treating the plasma by passing the plasma through an affinity column, wherein the affinity column comprises a matrix further comprising one or more affinity ligands immobilized thereto, wherein the one or more affinity ligands have binding specificity for the sialocomplexes, and wherein the one or more affinity ligands is an affinity ligand selected from the group consisting of anti-sTn mAb, anti-human MAG mAb, anti-human CD22 mAb, and a combination thereof.~~

44. The method of claim 43, further comprising eluting the sialocomplexes from the affinity matrix by contacting the affinity column with an elution buffer, resulting in a preparation comprised of isolated and purified sialocomplexes.

45. Isolated and purified sialocomplexes produced by the method according to claim 44.

] species
leaving